Overview of Long-Term Goal 3:
Air Quality Health Assessments

Background

The U.S. Environmental Protection Agency (EPA)'s air quality management program is one of the most successful environmental programs in the world. In the 30 years of the program's existence, air pollution has dramatically decreased. The direct benefits of the Clean Air Act (CAA) from 1970 to 1990 include reduced incidence of a number of adverse human health effects, improvements in visibility, and avoided damage to agricultural crops and other vegetation. These results have been accomplished in the face of a growing population, number of vehicles, and economy (See Figure 1). According to the Office of Management and Budget, the Clean Air Program is the largest nonmilitary Federal program in terms of cost and economic benefits to society. The Human Health Risk Assessment (HHRA) Program's Long-Term Goal (LTG) 3 contributes directly and significantly to this national effort to reduce the adverse health and ecological effects caused by air pollution, directly resulting in healthy communities that have clean air and sustainable ecosystems.

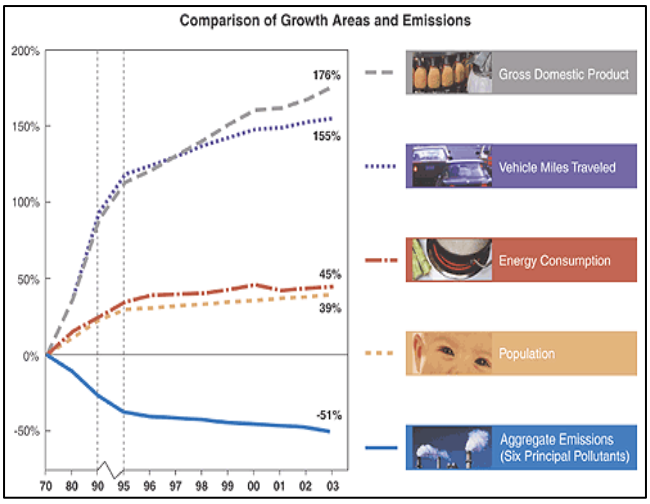

Figure 1. Comparison of growth areas and emissions

In spite of these successes, public health and the environment continue to be impacted by air pollution. More than 100 million people live in areas that exceed current air pollution standards and many ecosystems are imperiled by atmospheric pollutants. Children, people with preexisting diseases, and high-exposure groups are particularly at risk. Economically disadvantaged populations can experience higher exposures and can be at increased risk because they often reside in less desirable polluted areas (e.g., near freeways). Additionally, as science progresses more sensitive methods and a more robust understanding of human and ecologic health continue to reveal previously unknown impacts even while pollution levels are decreasing.

LTG 3 is a companion program to the Air and Human Health Research Multi-Year Plans (MYP). It must be noted that the research and technical contributions of the National Health and Environmental Effects Research Laboratory (NHEERL), the National Exposure Research Laboratory (NERL), and the National Center for Environmental Research (NCER) and their grantees are invaluable to our efforts. The scientific knowledge flowing from this combined research effort is utilized by the HHRA program, combined with other state of the science information, and articulated in the ISAs.

The purpose of this LTG 3 description is to portray, in concert with poster presentations, the program's relevance to EPA decision-making, leadership in risk assessment, exemplary scientific quality, and performance. Ongoing assessments are used to illustrate these attributes. Additionally, linkages to the assessments conducted in HHRA LTG 1, and the methods, models, and guidance developed under HHRA LTG 2, are highlighted below.

Relevance

This NCEA program executes the CAA mandate to "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health and the environment which may be expected from the presence of a pollutant in ambient air…." Based on the science elucidated and interpreted by NCEA, the Office of Air and Radiation (OAR) promulgates National Ambient Air Quality Standards (NAAQS) to protect public health and the environment with an adequate margin of safety. The CAA also mandates EPA to review periodically (every 5 years) the scientific bases (criteria) for setting the NAAQS for the six "critieria" air pollutants: particulate matter (PM), ozone (O_3), lead (Pb), oxides of nitrogen (NO_x), sulfur oxides (SO_x), and carbon monoxide (CO). Our analysis and evaluation of the latest scientific knowledge is documented in the Integrated Science Assessments (ISAs) (the streamlined version of the Air Quality Criteria Documents [AQCDs]) for each pollutant. Creation of an ISA proceeds as follows: (1) comprehensive review of all literature (thousands of multidisciplinary publications, (2) identification of key information, (3) performance of focused new analyses as needed, (4) integration of this body of literature to address the most policy-relevant questions, (5) articulation of key judgments and conclusions, and (6) documentation. The ISAs encompass science issues from source to dose to effect. These comprehensive evaluations routinely require NCEA scientists to undertake new analyses and make difficult judgments concerning interpretation of the science. This work places our scientists at the cutting edge of risk assessment. Making and documenting these scientific determinations are the fundamental work of NCEA.

Quality and Leadership

Creation of multidisciplinary knowledge, on the LTG 3 scale, is difficult and a relatively unique scientific activity. It requires experts that can collaborate and integrate across disciplines as diverse as atmospheric chemistry and physics, exposure, dosimetry, epidemiology, clinical medicine, toxicology, and ecological sciences. The quality of our work is seen in our innovative, solid analyses and crucial interpretations of the science. This work often leads the field in risk assessment science. Because of its direct connection to national policy-making, our scientific efforts, in both health and ecology, are more heavily scrutinized than scientific work conducted in any other setting, and must be sustained in the broader scientific community and in courts of law. The individual and collective quality of our science, and its far-reaching influence on science, policy, and law, make us national and international leaders in several applied sciences and risk assessment. HHRA leadership in the field of air pollution is illustrated in Table 1.

We have provided examples of the relevance, quality, and performance of our program in the abstracts and posters. Each poster highlights a new body of knowledge created by our scientists and is tied to important topics in the HHRA MYPs. An overview of the posters is provided below.

Table 1. NCEA Leadership in Risk Assessment

- **Advisors to senior management in EPA and other Federal agencies**
- **Advisors for WHO "Air Quality Guidelines"**
- **Advisors to PAHO and IARC**
- **Use of AQCDs/ISAs by international agencies and groups (EC, OECD, UN, etc.)**
- **Use of AQCDs/ISAs by national groups (Northeast States for Coordinated Air Use Management, State of California, Am. Lung Assn., etc.)**
- **Invitations for lectures and symposia**
- **Professional activities:**
  - **Leadership positions in professional societies**
  - **Workshop organizers and chairs**
  - **Editorial boards**
  - **Cross-agency committees**
  - **International working groups**
- **Publication in scientific journals**
- **Citations in the literature**

Poster 1: Integrated Science Assessments—The New NAAQS Process describes the Agency's revisions to this critical program to allow it to meet its mandated 5-year review schedule while ensuring a high level of scientific quality. In past years, substantial problems were encountered in meeting the schedule; several lawsuits have been brought against the Agency based on failure to complete reviews within 5 years. One significant change in this critical program is the new Integrated Science Assessment, a concise evaluation, integration, and interpretation of the most policy-relevant science for each criteria air pollutant. Several posters in the other LTGs describe the existing processes for development of "toxic" chemical assessments.

Two companion posters, **Poster 2: Atmospheric Chemistry and Physics Used in Integrated Science Assessments** and **Poster 3: Use of Exposure Science in the Integrated Science Assessments**, highlight the complex events that occur between emissions from the pollutant source to the exposure of the human or environmental populations. The atmospheric chemistry and physics of PM, O_3, NO_x, and SO_x are complex. Poster 2 describes some of the myriad difficulties in developing an indicator for each of these pollutants that would effectively represent critical exposures to ambient concentrations and help characterize the sources of each. NCEA scientists collaborate with scientists from the National Oceanic and Atmospheric Administration (NOAA) and from U.S. EPA's National Exposure Research Laboratory (NERL) to collect field data and perform large-scale numerical process modeling in efforts to identify pollutants, their transformation products, and possible NAAQS indicator species. Targeted approaches developed by NCEA scientists to understand the relationship between ambient concentrations and personal exposures are also presented. In addition, we explore comparisons across studies with differing exposure characteristics to untangle complex concentration-response relationships and identify causative agents. These efforts are related to an exposure poster in LTG 2.

Poster 4: Dosimetry of Criteria Pollutants in Integrated Science Assessments. This poster illustrates how we consider dosimetric issues to help unravel exposure-to-dose relationships, susceptibility, and species-to-species extrapolation. Our understanding of particle and gas dosimetry has been fostered by collaboration with the National Health and Environmental Effects Research Laboratory (NHEERL). NCEA routinely evaluates dosimetric issues to obtain improved estimates of target organ or tissue doses, which are then incorporated into HHRA assessments when sufficient data are available. Advances in dosimetry from EPA's Office of

Research and Development (ORD) have fueled substantial progress in the broader scientific community. Poster 4 is a companion to the posters dealing with pharmacokinetics data and modeling in LTG 1 (posters 8 and 10) and LTG 2 (posters 2, 3, and 11).

Poster 5: Use of Epidemiology and Human Clinical Studies in Integrated Science Assessments explores how direct evidence of human health effects can be used to provide compelling arguments for or against the need to revise or retain a standard for a criteria air pollutant. This requires careful integration, synthesis, and interpretation of the complex information provided by interdisciplinary human studies. In NCEA's assessments, the vast body of literature on the human health effects of air pollution is integrated and used to better characterize public health effects, to identify causative agents and susceptible populations, and to help characterize exposure, concentration, and dose-response interrelationships. Poster 5 in LTG 1 discusses similar issues for IRIS assessments.

Poster 6: Particulate Matter Provisional Assessment: Health Effects Literature Published 2002-2006. In 2006, we evaluated recent studies on the health effects of PM exposure with a focus on two areas: (1) epidemiological studies that used different size fractions ($PM_{2.5}$ or $PM_{10-2.5}$) and were conducted in the United States or Canada and (2) toxicological or epidemiological studies that compared the effects of PM from different sources, from different geographic locations, or having various size fractions and constituent components (also see LTG 3 posters 2 and 3). More than 700 peer-reviewed scientific papers were evaluated and integrated in a relatively short time (6 months). In the upcoming PM ISA (2008), we will consider over 6,000 papers. This assessment notes how various source categories in various locations can pose different health risks; this type of work has implications for community based risk assessments.

Poster 7: Ozone Air Quality Criteria Document: Mechanisms Underlying Health Effects notes how insights into mechanisms of action enabled us to relate on a process level such seemingly disparate findings as inflammation, susceptibility to infection, lung function changes, airways hyperresponsiveness, onset of asthma, hospitalization for respiratory disease, and mortality. Our description of ozone associated mortality has been a focal point of regulatory decision-making. Additionally, the underpinnings of susceptibility and concentration-response relationships are illuminated. We are drawing on mechanism of action information to increase our understanding of ozone and, more broadly, the effects of multipollutant exposures. Similar work is also noted in LTG 3 poster 8 below, and in LTG 1 posters 4, 6, and 7 and LTG 2 poster 6.

Poster 8: Lead Air Quality Criteria Document: Effects Below 10 µg/dL focuses on our recent efforts to described effects in two susceptible populations: children and persons with preexisting disease. With this recent review and synthesis of the scientific literature, disturbing new insights are now clear, with adverse effects observed below 10 µg/dL. Until recently, it was thought with the elimination of Pb in gasoline, that environmental concerns for Pb had largely been addressed and that a public health threat had been eliminated. In light of our recent efforts, current emissions from numerous industrial facilities are now of concern, as well as continued exposures from peeling paint and from soil and dust near roadways. Additionally, though the mean blood Pb in children is now ~1–2 µg/dL, hundreds of thousands of U.S. children, typically

in low socioeconomic status (SES) and in medically underserved communities, have blood Pb levels above 10 µg/dL. This poster, LTG 3 poster 10 (below), LTG 1 poster 7, and LTG 2 posters 4 and 5 all explore effects on sensitive subpopulations.

Poster 9: Oxides of Nitrogen Integrated Science Assessment: A Focus on Mixtures describes the complex relationship of NO_x atmospheric chemistry issues, human exposure, and health effects. One of the principal considerations in the setting of the primary NAAQS for nitrogen dioxide (NO_2) is the issue of mixtures. Oxides of nitrogen are a complex mixture in and of themselves. Additionally, ambient NO_2 generally behaves very much like a traffic-generated pollutant in urban areas, showing spatial and temporal variability consistent with that expected from traffic-generated pollutant mixtures, including CO and PM. This makes it difficult to isolate health effects that are solely attributable to NO_2 from those that may result from the mixture. This poster explores these complex issues and summarizes the preliminary results from the first draft of the NO_x ISA. LTG 2 posters 9 and 10 also explore mixtures.

Poster 10: Sulfur Oxides Integrated Science Assessment: Evaluating the Concentration—Time-Response Relationships in a Susceptible Population reviews epidemiologic and human clinical studies of exposure that indicate increased SO_2 susceptibility in certain populations. A number of complex issues are explored: the potential for response at low-exposure levels, responses of susceptible vs. general populations, integrating clinical evidence with epidemiologic evidence, and the relationship between exposure level, duration of exposure, and response. In this poster we explore these complex issues and their potential impacts on risk assessment. LTG 1 poster 11 and LTG 2 poster 8 also explore concentration-time-response issues. LTG 1 poster 7 and LTG 2 posters 4 and 5 also explores the issues of sensitive subpopulations.

Poster 11: Oxides of Nitrogen and Sulfur Oxides Integrated Science Assessment of the Secondary Standard: Ecological Effects highlights our environmental work in LTG 3. In a move toward assessing real-world mixtures, we consider the ecological effects of NO_x and SO_x in tandem, as part of a joint review of the secondary NAAQS for NO_2 and SO_2. This effort is a prime example of expanding single substance risk assessment to the complex environment. This multipollutant approach is designed to address acidification of ecosystems, a process that is driven by exposure to both NO_x and SO_x. NO_x acts in concert with other sources of reactive nitrogen (fertilizers, sewage, and atmospheric NO_y) to cause "nitrogen pollution," resulting in a suite of terrestrial and aquatic ecological problems including biodiversity losses, disease, and eutrophication with harmful algal blooms.

Poster 12: Data Resources Supporting Integrated Science Assessments elaborates on one part of the new NAAQS process described in poster 1. As part of the new process, NCEA is charged with developing and implementing a continuous process to identify, compile, characterize, and prioritize new scientific studies with the assistance of state-of-the-art electronic databases. This poster describes our progress in building the ongoing, "evergreen" database. Once fully operational, this new database will provide a valuable resource to the scientific community and to the broader public on the current state of the literature, particularly on those studies considered to provide information useful in addressing the policy relevant questions under consideration.

To ensure the quality of our efforts, HHRA LTG 3 products are reviewed by internal and external groups that include (1) an Intra-Agency Working Group, which includes scientists from other parts of ORD, the Regions, and the Program Office(s); (2) an Inter-Agency Working Group, the Committee on the Environment and Natural Resources (all Federal Agencies); and (3) the CASAC. The CASAC reviews several interrelated products: the initial plan (identifies policy-relevant questions), the first and second drafts of the ISA, the exposure-risk assessment (conducted by the Program Office) that is based on NCEA's ISA, and the science in the Advanced Notice of Proposed Rulemaking (ANPR) itself. As many as 8 to 10 CASAC meetings are scheduled in the upcoming year. Stakeholders have opportunities to comment at each of these steps. Quality of the AQCDs/ISAs is realized by the careful, thoughtful integration of the relevant science in the areas of atmospheric chemistry, exposure, toxicology, epidemiology, ecology, and welfare effects.

Program Performance

The HHRA assessments are the "gold standard" for assessments around the world. The knowledge and judgments of the HHRA staff have been and will be tested beyond the experience of most scientists by rigorous scientific review, international opinion, and in courts of law including up to the Supreme Court (e.g. American Trucking Association & U.S. Chamber of Commerce & Equipment Manufacturing Institute, etc. v. Browner, Whitman v. American Trucking Associations, and American Trucking Associations v. Whitman). For 30 years, NCEA has met the standard dictated by law, i.e., that our assessments "reflect the latest scientific knowledge." The EPA has never lost a court case nor had a decision overturned due to a flaw in our scientific assessments. The remarkable achievements of this program depend on the quality, performance, and leadership of HHRA scientists.

Table 2 shows our 2006 and 2007 Annual Performance Measures (APMs), which are being timely met with high-quality documents. AQCDs/ISAs are traditionally followed immediately by Program Office action with the initiation of an exposure and risk assessment. NCEA scientists also provide technical support to the Program Office and advice to Office Directors, Assistant Administrators, the Deputy Administrator, and Administrator. In his press conference on the O_3 ANPR, Administrator Johnson specifically acknowledged the support he received from Agency's scientists and how much he valued their guidance. HHRA staff are routinely awarded recognition for their work, e.g., through receipt of EPA Gold Medals for exemplary service. In addition, AQCD/ISA documents have widespread effects, being cited and used in the scientific community; public state, local, and tribal governments; and private, public, and international groups at large.

Table 2. LTG 3 APM Status

APMs	*Status*	*Year*
Ozone AQCD (final)	**met**	**2006**
Lead AQCD (final)	**met**	**2006**
NO_x ISA—health (ERD)	**met**	**2007**
SO_x ISA—health (ERD)	**met**	**2007**
NO_x/SO_x ISA—ecology (ERD)	**on track**	**2008**
PM ISA (ERD)	**on track**	**2008**

Conclusions

The direct benefits of the CAA from 1970 to 1990 include reduced incidence of a number of adverse human health effects, improvements in visibility, and avoidance of damage to agricultural crops. The estimated economic value of these benefits ranges from $5.6 trillion to $49.4 trillion, in 1990 dollars, with a mean of $22.2 trillion. A more specific example is provided by Figure 2, which shows the percentage of all children (ages 5–18) engaged in moderate exertion that are estimated to experience a decrease in lung function associated with O_3 exposure. Figure 2 illustrates the public health impacts in various cities at O_3 levels at which the standard could be set.

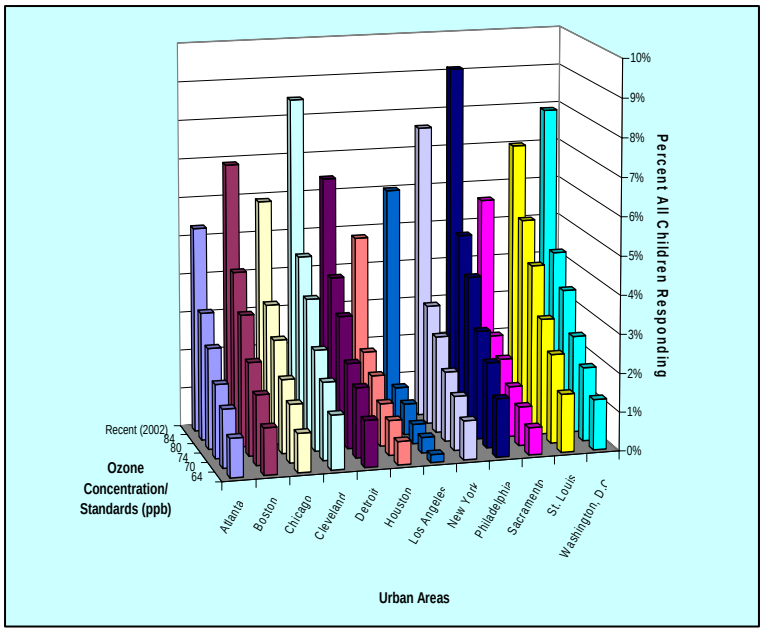

Figure 2. The percentage of all children (ages 5–18) in various cities engaged in moderate exertion that are estimated to experience a decrease in lung function associated with O_3 exposure

In conclusion, LTG 3 has provided the scientific bases for the Agency's national ambient air quality standards for criteria air pollutants. These standards are essential to EPA's efforts to attain the goal of clean air. Thus, LTG 3 has made dramatic contributions toward achieving healthy communities and sustainable ecosystems. The assessments produced in LTG 3 are the international standard and are used by other countries and international organizations. These results have been made possible by a high-performing staff and a high-quality assessment program. LTG 3 continues to be positioned to elucidate and resolve some of the most complex environmental problems. Its chemical-specific risk assessments are robust prototypes for the improvement of human health risk assessments. In particular, LTG 3 is leading advances in quantitative risk assessment and dosimetry and in characterizing mechanism of action, susceptible subpopulations, and the health effects of pollutant mixtures. Moreover, through NCEA's research, outreach, and education, we contribute to the elucidation and resolution of some of the most complex pressing environmental problems that we now face.